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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,633	12/19/2001	Daniel D. Gallaher	600.523US1	4606

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EXAMINER

EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,633

Applicant(s)

GALLAHER ET AL.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's information disclosure statements, filed, December 19, 2001 and May 19, 2003.

Acknowledgement is made of the receipt of applicant's drawings, filed April 8, 2002.

Acknowledgement is made of the receipt of applicant's response to restriction requirement, filed July 14, 2003, wherein applicants elected Group I, claims 1-74, without traverse.

Claims 1-74 are active in this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 9, 22-24, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinto (WO 98/50398 A1). The claims are directed to methods of

reducing the percentage of body fat in a human via administration of indigestible, viscous polysaccharides and beta-glucans.

Pinto teaches a beta-glucan having higher viscosity and molecular weights which shows benefits in weight reduction by providing longer periods of satiety (page 5, lines 11-12). The beta-glucans of the referenced invention are useful in food products such as dietary confections, jellies, gum drops, cereals, snacks, pasta and yogurt (page 6, lines 15-19).

Pinto teaches every aspect of the cited claims. Thus, Pinto anticipates claims 1, 6, 9, 22-24, 36 and 37.

Claims 1-6, 9, 13, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jamas et al (US 6,143,731).

Jamas discloses compositions useful in the treatment of weight loss comprised of whole beta-glucans (column 6, lines 65-67). Whole beta-glucans are wholly composed of glucose units bonded together by $\beta(1-3)$ and $\beta(1-6)$ glycosidic linkages (column 4, lines 56-59). The referenced composition can be administered orally, in liquid or solid form (column 7, lines 8-9). Liquid formulations generally contain about 5 grams whole glucan per 8 fluid ounces (column 7, lines 16-17).

Jamas teaches every aspect of the cited claims. Thus, Jamas anticipates claims 1-6, 9, 13 and 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischner (US Publication 2003/0039708 A1). The claims are directed to a method of reducing body fat in a human wherein the polysaccharide is locust bean gum, guar gum, carrageenan, alginate, modified cellulose, beta-glucan or glucomannan.

Fleischner teaches a composition used for weight loss comprised of glucomannan (Abstract; page 2, paragraph 0025; and claim 1). The said composition is for use by humans (page 4, claim 1).

Fleischner teaches every aspect of claims 1, 6 and 22. Therefore, Fleischner anticipates these claims.

Claims 38, 41, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Portman (US Publication 2002/0019334 A1). The claims are directed a method of

reducing body fat by administering a composition comprised of hydroxypropylmethylcellulose (HPMC).

Portman teaches a nutritional composition comprised of soluble fibers such as hydroxypropylmethylcellulose (page 4, paragraph 0059). The soluble fibers are present in the range of 0.10 to 5.0 grams, more preferably in the range of 1.0 to 4.0 grams (page 4, paragraph 0060).

Portman teaches every aspect of claims 38, 41 and 50. Therefore, Portman anticipates the aforementioned claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the

obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-37 and 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al (US 6,143,731) in view of Pinto (WO 98/50398) or Portman (US Publication 2002/0019334 A1). The claims are directed to methods of reducing the percentage of body fat in a human via administration of indigestible, viscous polysaccharides, beta-glucans and hydroxypropylmethylcellulose. The method also includes reducing the level of leptin in the bloodstream of a mammal using indigestible polysaccharides.

In view of the 102(b) discussion above, Jamas further teaches that the beta-glucan containing composition can be included as part of a complete nutritional food (column 7, line 13). While Jamas does not enumerate specific examples of the food items, Pinto demonstrates, however, that beta-glucan-containing foods can be developed into cereals, snacks, pasta and yogurt (Pinto, page 6, lines 15-19). It would have been obvious for one of ordinary skill in the art to formulate this composition into various edible embodiments such as cereals or snacks, thus providing a range of possible alternatives for the subject in need of the composition.

Pursuant to Example 12 (column 15 bridging column 16), the test subjects that were administered the whole glucan diet, demonstrated weight loss results during a 20-day regimen. A 20-day regimen is equivalent to approximately 3 weeks. Referring to Table 11, the diet group fed whole glucan experienced weight loss equivalent to approximately 21 grams -- 21 grams translates into approximately an 18.8% reduction (column 15, Table 11).

Portman teaches a nutritional composition comprised of soluble fibers such as hydroxypropylmethylcellulose (page 4, paragraph 0059). The soluble fibers are present in the range of 0.10 to 5.0 grams, more preferably in the range of 1.0 to 4.0 grams (page 4, paragraph 0060). Portman discloses that there was a weight loss effect demonstrated over a period of 6 weeks (page 7, paragraphs 0095-0106). The disclosed composition may be used as a food additive to foods selected from the consisting of yogurt, jello, applesauce, cottage cheese, cereal, bread and candy bars (page 7, paragraph 0084).

The cited prior art patent does not expressly teach a reduction in leptin, however, studies have shown that there is a positive correlation between leptin and body weight. Andrico et al (Human Reproduction, Abstract, August 2002) is provided to demonstrate that relationship. Accordingly, if the claimed beta-glucan composition can be utilized to reduce body fat, the same beta-glucan composition can be utilized to reduce the amount of leptin in the subject.

Claims 38-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portman (US Publication 2002/0019334 A1) in view of Bahram et al (*Native and Partially Hydrolyzed Psyllium Have Comparable Effects on Cholesterol Metabolism in Rats*, J. Nutrition, March 1997; 27, 3; page 463). In view of the 102(e) discussion above, Portman further discloses that there was a weight loss effect demonstrated over a period of 6 weeks (page 7, paragraphs 0095-0106). The disclosed composition may be used as a food additive to foods selected from the consisting of yogurt, jello, applesauce, cottage cheese, cereal, bread and candy bars (page 7, paragraph 0084).

One of ordinary skill in the art would be motivated to modify the teachings of the cited art with the expectation of formulating an optimized composition to be used for weight loss.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans
Examiner
Art Unit: 1615

September 5, 2003


THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER